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510(k) SUMMARY

V1 SYSTEM

1 General Information

- Applicant:

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Establishment Registration No: 8010047

- Official Correspondent:

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- Manufacturer:

OLYMPUS MEDICAL SYSTEMS CORP.
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Tokyo, JAPAN 190-0182
Establishment Registration Number: 3003637092

2 Device Identification

- Device Trade Name: V1 SYSTEM
- Common Name: Endoscopic Video Imaging System
- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: FDF, FDS

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3 Predicate Device Information

Subject Device (Part of this Submission)	Predicate Device	PD's 510(k) No.
VIDEO SYSTEM CENTER OLYMPUS CV-V1	EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180	K100584
	EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180	K100584
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-LV1 (Hereinafter referred	EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE Q180	K100584
COLONOVIDEOSCOPE OLYMPUS CF- LV1L (Working Length: 1680mm) and CF-LV1I (Working Length: 1330mm)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AL	K100584

4 Device Description

V1 SYSTEM

The primary components of the V1 SYSTEM consists of two Olympus colonovideoscopes; CF-LV1L and CF-LV1I (which are identical except for their working) lengths, an Olympus gastrointestinal videoscope; GIF-LV1 and a video system center. This system is intended for endoscopic diagnosis, treatment and video observation of the upper and lower digestive tract. The V1 SYSTEM is designed to be used with specified monitors, EndoTherapy accessories and other ancillary equipment.

The primary components of the subject system, which are part of this submission, are:
VIDEO SYSTEM CENTER OLYMPUS CV-V1
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-LV1
COLONOVIDEOSCOPE OLYMPUS CF-LV1L
COLONOVIDEOSCOPE OLYMPUS CF-LV1I

CV-V1

CV-V1 can be used with Olympus endoscope models, such as gastorointestinal videoscope GIF-LV1 and colonovideoscope CF-LV1L/I. The subject premarket notification is specific for gastrointestinal videoscopes and colonovideoscopes.

GIF-LV1, CF-LV1L/I

The GIF-LV1, CF-LV1L/I can be used with VIDEO SYSTEM CENTER OLYMPUS CV-V1. The light source and the LG bundle are not used, instead, there are LEDs in the distal end of the scope that runs by electric power from the CV-V1 and light up the distal end. The newly designed one-touch connector is water proof.

5 Indications for Use

VIDEO SYSTEM CENTER OLYMPUS CV-V1

This video system center is intend to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.

The indications include the applicability of endoscopy and endoscopic treatment.

GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-LV1

This instrument is intended to be used with an Olympus video system center, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery and is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

COLONOVIDEOSCOPE OLYMPUS CF-LV1L and CF-LV1I

This instrument is intended to be used with an Olympus video system center, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery and is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

6 Comparison of Technological Characteristics

The V1 SYSTEM is basically identical to the predicate device in intended use, and similar in specifications.

Video System Center:

When compared to the predicate device, the subject device has the similar technological features such as the video signal output, automatic gain control/ iris mode function and air feeding pump. There are differences in the input current and compatible endoscopes, however, these differences are considered as minor.

Endoscope:

When compared to the predicate device, the subject device has the similar technological features such as the depth of field, direction of forward view, bending section angulation and inner diameter of instrument channel. There are differences in the field of view, lighting method and outer diameter of distal end/ insertion tube, however, these differences are considered as minor.

The following non-clinical test and usability studies were performed.

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7 Substantially Equivalent Discussion

The subject device, V1 SYSTEM, is a modification to LED lightning system. The indications for use, principles of operation and fundamental technology of the V1 SYSTEM are similar to the predicate devices.

The major difference from the predicate devices is lighting method as follow:

- The subject device is provided LED in the endoscopes and the Video Processor is able to supply power for the LED.
- The predicate device (K100584) has the light guide cable in endoscopes and the light source is able to supply light.

The newly lighting method has been confirmed that the safety and effectiveness are equivalent compare with the predicate devices.

The CV-V1 and the GIF-LV1 and CF-LV1L/I are similar in method of operation and design as the predicate devices. In addition, similar or identical materials are used and biocompatibility results were provided.

8 Summary of Non-Clinical Testing

The following non-clinical test and usability studies were performed.

Basic safety and performance testing was performed in accordance with IEC 60601-1, 60601-1-1, 60601-1-2, 60601-2-18. In addition, verification and comparison studies were conducted to evaluate the mechanical and functional performance. Specially, test results in the following areas were provided.

Biocompatibility

Intracutaneous Reactivity Test.doc
Cytotoxicity Study.doc
Skin Sensitization Test.doc

The following standards were used during the design and validation of the subject devices.

1) IEC 60601-1: 1988, A1: 1991, A2: 1995
2) IEC 60601-1-1: 2000,
3) IEC 60601-1-2: 2007
4) IEC 60601-2-18: 1996, A1: 2000
5) ISO 14971: 2007
6) ASTM E1837-96: 2007
7) ANSI/AAMI/ISO 11135-1: 2007
8) ISO 10993-1: 2009
9) ISO 10993-5: 2009
10) ISO 10993-10: 2002
11) ISO 10993-11: 2006

The risk analysis was carried out I accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of their risk analysis assessment.

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9 Conclusion

When compared to the predicate device, the V1 SYSTEM does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Stacy Abbatiello Kluesner, M.S., RAC
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CENTER VALLEY PA 18034

MAR 20 2012

Re: K111756
Trade/Device Name: V1 SYSTEM
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: February 24, 2012
Received: February 27, 2012

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: V1 SYSTEM

Indications For Use:

VIDEO SYSTEM CENTER CV-V1

This video system center is intend to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.

GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-LV1

This instrument is intended to be used with an Olympus video system center, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery and is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

COLONOVIDEOSCOPE OLYMPUS CF-LV1L and CF-LV1I

This instrument is intended to be used with an Olympus video system center, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery and is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111756